Summary of Oral Presentation FDA Public Hearing April 20-21, 2015

Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory
Framework After a Quarter-Century

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Pursuant to the Food and Drug Administration (FDA) Federal Register Notice of public hearing (Notice), Docket No. FDA-2015-N-0540, the National Center for Homeopathy provides the following views that will be presented on behalf of consumers of homeopathic products at the April 20-21, 2015 public hearing.

National Center for Homeopathy

Founded in 1974, the National Center for Homeopathy (NCH) is a 501(c)3 not-for-profit organization dedicated to promoting health through homeopathy by advancing the use and practice of homeopathy. NCH supports education in, awareness of, and increased access to homeopathy. We have the largest, most diverse supporter base in the homeopathic community and we are the national go-to resource for all who are interested in learning about homeopathy.

FDA Questions for Discussion

The following questions (text in bold) are quoted from FDA's Notice Docket No. FDA-2015-N-0540. A response outline is provided for each question that we will address during the public hearing.

Question 1: What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

- The FDA notice states that "the homeopathic drug industry has continued on an upward growth trajectory since the FDA issued its Compliance Policy Guide (CPG) in 1988.
- There is a large and growing group of consumers interested in exploring ways to care for their health naturally, both at home and under the care of professionals.
- There has also been an increased demand by consumers for information about homeopathy, which is reflected in the upward growth trajectory of the NCH community.
- For example, over the last 18 months, our supporter-base, website traffic, social media following and use of other consumer resources has increased significantly.
- Our interactions with consumers indicate that consumer attitudes about homeopathic products are very positive.
- Consumers greatly appreciate the opportunity for *choice* when selecting over the counter remedies.
- The accessibility of homeopathic remedies over the counter is a major factor in this level of satisfaction.

Question 2: Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic? If not, what information, including, for example, information in labeling, would allow consumers and health care providers to be better informed about products labeled as homeopathic?

• NCH serves an ever-growing community of consumers interested in making informed decisions about their health care, including the use of homeopathic drug products.

- Consumers are confident in their abilities to make informed decisions about homeopathic products.
- As the homeopathic organization most visible to the public, we receive calls and inquiries from
 consumers every week about homeopathy. We do not receive inquiries from consumers expressing
 confusion about these over the counter products or requesting additional information to assist them
 in making a decision about using a product labeled as homeopathic.
- If consumers routinely experienced confusion about homeopathic drug products when making purchase decisions about over the counter products, we would receive inquiries about this issue.

Conclusion

We appreciate the opportunity to participate in this hearing and are confident that the views expressed herein are consistent with the interests of public health.